APR 0 5 2004

B 1616\$

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
D'AMATO ET AL.)) Art Unit: 1616
Serial No. 09/780,650) Examiner: BADIO, B.
Filed: FEBRUARY 12, 2001)
For: ESTROGENIC COMPOUNDS AS)

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

The citation of information on the attached Form PTO/SB/08A, "List of Art Cited by Applicant" is made pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98. A copy of each cited item is enclosed.

As this Information Disclosure Statement is being filed after the issuance of an office action on the merits, pursuant to 37 C.F.R. §1.97(c)(2), the fee of \$180, as set forth in §1.17(p), is enclosed.

Related applications are listed on the attached Supplemental Appendix A for your reference. Applicants respectfully request that the Examiner review the applications listed in Appendix A, initial Appendix A in the appropriate spaces, and return a copy of the initialized Appendix to Applicants.

The citation of this information does not constitute an admission of priority or that any cited item is available as a reference, or a waiver of any right the applicant may have under applicable statutes, Rules of Practice in patent cases, or otherwise.

KILPATRICK STOCKTON LLP 1100 Peachtree Road, Suite 2800 Atlanta, Georgia 30309-4530 (404) 815-6500

Our Docket: 05213-0493 (43170-253692)

Respectfully submitted

Robert E. Richards, Reg. No. 29,105

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria,

VA 22313-1450, on April , 20

Robert E. Richards Reg. No. 29,105

In re Applica	ation of:)
D'AMATO	ET AL.) Art Unit: 1616
Serial No.	09/780,650	Examiner: BADIO, B.
Filed:	FEBRUARY 12, 2001)
	ROGENIC COMPOUNDS AS ANTI- OTIC AGENTS))

APPENDIX A

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicants respectfully request that the Examiner review the below-listed patent applications. Please review and initial each listed application and return a copy of the initialed Supplemental Appendix A to the Applicants.

The serial numbers of the below-listed U.S. patent applications are listed on this form as provided in MPEP §609(D), rather than a PTO-1449 form, to avoid the serial numbers of the pending U.S. patent applications being published on any patent that may issue from this application. Applicants do not waive the confidential nature of any of the below-listed patent applications.

	_ 1.	U.S. Application Serial No. 09/641,327 filed August 18, 2000
~···	_ 2.	U.S. Application Serial No. 09/644,387 filed August 23, 2000
	_ 3.	U.S. Application Serial No. 09/779,331 filed February 8, 2001
	_ 4	U.S. Application Serial No. 09/899,702 filed July 5, 2001
	_ 5	U.S. Application Serial No. 09/939,208 filed August 24, 2001
	6	U.S. Application Serial No. 10/077,142 filed February 15, 2002

Our Docket: 05213-0493 (43170-253692)

Filed: February 12, 2001

	7	U.S. Application Serial No. 10/080,076 filed February 21, 2002
	8	U.S. Application Serial No. 10/281,831 filed October 25, 2002
	9	U.S. Application Serial No. 10/354,921 filed January 30, 2003
	10	U.S. Application Serial No. 10/354,927 filed January 30, 2003
	11	U.S. Application Serial No. 10/375,890 filed February 27, 2003
	12.	U.S. Application Serial No. 10/610,748 filed July 1, 2003
	13.	U.S. Application Serial No. 10/617,150 filed July 10, 2003
	14.	U.S. Application Serial No. 10/635,846 filed August 5, 2003
	_15	Unassigned U. S. Application filed February 27, 2004 under Attorney Docket No: 05213-3001 (43170-295490)

Respectfully Submitted,

Bv:

Robert E. Richards Reg. No. 29,105

KILPATRICK STOCKTON LLP 1100 Peachtree Road Suite 2800 Atlanta, Georgia 30309/4530 (404) 815-6500

Our Docket: 052130-0493 (43170-253692)

PTO/SB/08A (08-00)

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of

Application No.	09/780,650
Filing Date	02/12/2001
First Named Inventor	D'Amato
Group Art Unit	1616
Examiner Name	Badio, Barbara P.
Attorney Docket Number	05213-0493 (43170-253692)

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Application No.	09/780,650			
Filing Date	02/12/2001			
First Named Inventor	D'Amato			
Group Art Unit	1616			
Examiner Name	Badio, Barbara P.			
Attorney Docket Number	05213-0493 (43170-253692)			

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid of number Complete if Known 09/780,6 Application No. Substitute for Form 1449/A/PTO 02/12/200 Filing Date INFORMATION DISCLOSURE First Named Inventor D'Amato STATEMENT BY APPLICANT 1616 Group Art Unit (use as many sheets as necessary) Badio, Barbara P. **Examiner Name** 05213-0493 (43170-253692) 31 Attorney Docket Number 3 of Sheet FOREIGN PATENT DOCUMENTS Date of Publication Foreign Patent Document Pages, Columns, Lines, Where T⁶ Cite Examiner of Cited Document Relevant Passages or Kind Code Name of Patentee or Initials No. Relevant Figures Appear MM-DD-YYYY Office3 Applicant of Cited Document Number⁴ (if known) 10/23/1969 46 DE 1907330 Sandoz Ltd. (Identifier only) 09/10/1970 No 47 DE 2 004 516 VEB Jenapharm 12/19/1977 48 DE 27 57 157 Schering AG 01/28/1988 Schering A.-G (Identifier only) 49 DE 3625315 08/01/1986 50 **EPO** 0166937 A2 Abbott Laboratories 12/29/1960 GB 857,080 Syntex S.A. 12/29/1960 52 GB 857,081 Syntex S.A. 07/02/1980 Takeda et al. 53 GB 1,570,597 DAINIPPON PHARM CO LTD 01/18/1967 54 JP 42-928 В (abstract only) No В Teikoku Hormone Mfg. Co. 55 JP 39-5480 08/03/1999 No 56 JP 11-209322 No Lilly & Co Eli (Elil) 08/06/1983 57 JP 58-131978 Research Development Corp. of 04/21/1988 58 JP 63090763 Α Japan (Abstract only)

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Signature	Considered	

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number Complete if Known 09/780,650 Application No. Substitute for Form 1449/A/PTO 02/12/2001 Filing Date NFORMATION DISCLOSURE First Named Inventor D'Amato ATEMENT BY APPLICANT 1616 Group Art Unit (use as many sheets as necessary) **Examiner Name** Badio, Barbara P. Attorney Docket Number 05213-0493 (43170-253692) of 31 9 OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Examiner Cite item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Initials No. publisher, city and/or country where published Title: Orally Active Long-Acting Estrogen (AY-20,121) Author: BANIK et al. 96 (3-(2-propynyloxy)-estra-1,3,5,(10)-triene-17. beta.-ol trimethylacetate) (Identifier Publ: Steroids Pages: 289-296 Date: 1970 Vol/Iss: 16 (3) Title: Steroid Receptor-Mediated Cytotoxicity of an Antiestrogen and an Antiprogestin in Author: BARDON et al. Breast Cancer Cells (Abstract only) Publ: Cancer Research Pages: 1441-1448 03/01/87 Date: Vol/Iss: 47 (5) Title: Tumor Necrosis Factor Production in Patients with Leprosy Author: BARNES et al. 98 Publ: Infection and Immunity Pages: 1441-1446 Vol/Iss: 60 (4) Date: 04/1992 Title: Studies in Antifertility Agents. 8. Seco Steroids. 2. 5,6-Secoestradiol and Some Related 99 Author: BINDRA et al. Compounds Publ: Journal of Medicinal Chemistry Pages: 921-925 Date: 1975 Vol/lss: 18 (9) Title: Raf-1/bcl-2 Phosphorylation: A Step from Microtubule Damage to Cell Death 100 Author: BLAGOSKLONNY et al. |Publ Cancer Research Pages: 130-135 Date: 01/01/97 Vol/Iss: 57 Title: Synthesis of Some Analogs of Estradiol Author: BLICKENSTAFF et al. Publ: Steroids 5 4 1 Pages: 889-902 Vol/lss: 46 (4,5) Date: 10/1985 Title: Some Preliminary Synthetical Studies with 5,6,7,8-Tetra-hydro-8-methylindane Author: BOYCE et al. 102 -1,5-dione Publ: Unknown Pages: 4547-4553 Vol/Iss: Date: 1960

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		Publ:	gliomas				
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	106	Author: BROSENS et al.			ogenic Effect of Eth	inylestradiol and M	estranol on the
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	108	Author: CAMBIE et al.		eroids. Part II. Chr 5(10)-trienes	omium Trioxide Ox	idation of Some	
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		Journal of the Chemical Society			Pogost 1224 12	140 Page	4000
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Complete if Known 09/780,650 Application No. tie for Form 1449/A/PTO 02/12/2001 Filing Date INFORMATION DISCLOSURE First Named Inventor D'Amato STATEMENT BY APPLICANT Group Art Unit 1616 (use as many sheets as necessary) **Examiner Name** Badio, Barbara P. Attorney Docket Number 05213-0493 (43170-253692) Sheet of 31 13 OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Examiner Cite item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Initials No. publisher, city and/or country where published Title: Sex Hormone-Binding Globulin Mediates Prostate Androgen Receptor Action via a Author: DING et al. 124 Novel Signaling Pathway (Abstract only) Publ: Endocrinology Pages: 213-218 Date: Vol/Iss: 139 (1) 1998 Title: Seco-Oestradiols and Some Non-Steroidal Oestsrogens: Structural Correlates of Author: DURANI et al. 125 Oestrogenic Action Journal of Steroid Biochemistry Pages: 67-77 Date: 1979 Vol/Iss: 11 Title: Thin-layer Chromatography of DANSYL-oestrogens Author: DVIR et al. 126 Journal of Chromatography Pages: 505-506 Vol/Iss: 52 Date: 11/04/70 Title: Synthese von Ostradiol (in German - No translation available) Author: EDER et al. 127 Publ: Chem. Ber. Pages: 2948-2953 Date: Vol/lss: 109 1976 Title: Synthesis, Uterotropic, And Antiuterotrophic Activities & Some Estradiol Derivatives 128 Author: EL-TOMBARY. Containing Thiadiazole, Thiazoline, ad Thiazolidinone Moieties Publ: Arch. Pharm. Pharm. Med. Chem. Pages: 295-302 Vol/lss: 330 (9-10) Date: 1997 Title: Modulation der hypophysaren Sekretion von Luteinisierendem Hormon (LH) durch 129 Author: EMONS et al. Ostrogene Publ: FOCUS MHL Vol/Iss: 3 Pages: 221-228 Date: 1986 Title: Microtubular Proteins as Cellular Targets for Carcinogenic Estrogens and Other Author: EPE et al. Carcinogens Publ: Mechanisms of Chromosome Distribution and <u>Aneuploidy</u> Pages: 345-351 Vol/Iss: Date: 1989

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the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number Complete if Known Application No. 09/780.650 Substitu for Form 1449/A/PTO 02/12/2001 Filing Date INFORMATION DISCLOSURE First Named Inventor D'Amato STATEMENT BY APPLICANT Group Art Unit 1616 (use as many sheets as necessary) **Examiner Name** Badio, Barbara P. Attorney Docket Number 05213-0493 (43170-253692) of Sheet 31 15 OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Examiner Cite Τ'n item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Initials No. publisher, city and/or country where published Title: Angiogenesis Inhibition and Tumor Regression Caused by Heparin or a Heparin Author: FOLKMAN et al. 138 Fragment in the Presence of Cortisone Publ: Science Pages: 719-725 Date: 08/19/83 Vol/Iss: 221 Title: Tumor Angiogenesis: Therapeutic Implications Author: FOLKMAN, J. 139 Publ: New England Journal of Medicine Pages: 1182-1186 Vol/Iss: 285 (21) Date: 11/18/71 Title: Induction of Angiogenesis During the Transition from Hyperplasia to Neoplasia 140 Author: FOLKMAN, J. et al. Publ: Nature Pages: 58-61 Date: 05/04/89 Vol/Iss: 339 Title: Tumor Behavior in Isolated Perfused Organs in vitro Growth and Metastases of 141 Author: FOLKMAN, J. et al. Biopsy Material in Rabbit Thyroid and Canine Intestinal Segment Publ: Annals of Surgery Vol/Iss: 164(3) Pages: 491-502 Date: 09/01/66 Title: The Endogenous Oestrogen Metabolite 2-Methoxyoestradiol Inhibits Angiogenesis and Author: FOTSIS et al. Suppresses Tumour Growth Publ: <u>Nature</u> Pages: 237-239 Date: 03/17/94 Vol/Iss: 368 Title: Generation, Characterization, and Deprotonation of Phenol Radical Cations Author: GADOSY et al. 143 Publ: Journal of Physical Chemistry Vol/Iss: 103 Pages: 8834-8839 Date: 1999 Title: Mannich Reaction of Estrone Author: GANDHI et al. 144 Journal of Indian Chem. Soc. Pages: 306-308 Date: 1962 Vol/Iss: 39

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Complete if Known Application No. 09/780,650 Substitute for Form 1449/A/PTO 02/12/2001 Filing Date INFORMATION DISCLOSURE First Named Inventor D'Amato STATEMENT BY APPLICANT 1616 Group Art Unit (use as many sheets as necessary) **Examiner Name** Badio, Barbara P. Attorney Docket Number 05213-0493 (43170-253692) Sheet of 31 29 OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Cite Examiner item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Initials No. publisher, city and/or country where published Title: Methylation of Catechol Estrogen with Diazomethane Author: TERANISHI, M. et al. 236 Publ: Chemical and Pharmaceutical Bulletin Pages: 3309-3314 Vol/lss: 31 (9) Date: 09/1983 Title: Microtubule-Active Drugs Taxol, Vinblastine, and Nocodazole Increase the Levels of 237 Author: TISHLER et al. Transcriptionally Active p53 Publ: Cancer Research Pages: 6021-6025 Date: 12/15/95 Vol/Iss: 55 Title: A Convenient Synthetic Method for Alpha-Alkylation of Steroidal 17-Ketone: Author: TREMBLAY et al. 238 Preparation of 16β-(THPO-Heptyl)-Estradiol Publ: Synthetic Communications Pages: 2483-2495 Date: Vol/Iss: 25 (16) 1995 Title: Synthesis of 16-(Bromoalkyl)-Estradiols Having Inhibitory Effect on Human 239 Author: TREMBLAY et al. Placental Estradiol 17β-Hydroxysteroid Dehydrogenase (17β-HSD Type 1) Publ: Bioorganic & Medicinal Chemistry Pages: 505-523 Date: 1995 Vol/lss: 3 (5) Title: The Synthesis of 2- and 4-Fluoroestradiol 240 Author: UTNE et al. Publ: Journal of Organic Chemistry Pages: 2469-2473 Date: 06/1968 Vol/lss: 33 (6) Title: Structure of 11.beta.-(4-(dimethylamino)phenyl)-17.beta.-hydroxy-17. alpha.-(2-Author: VAN GEERESTEIN et al. 241 propenyl) estra-4,9-dien-3-one (Identifier only) Publ: Acta Crystallogr., Sect. C: Cryst. Struct. Commun. Pages: 319-322 Date: 1987 Vol/lss: C43 (2) Title: In Vitro Activity of Thalidomide Against Mycobacterium avium Complex Author: VICENTE et al. 242 Archives of Internal Medicine Pages: 534 Vol/Iss: 153 (4) Date: 02/22/93

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Complete if Known Application No. 09/780,650 ite for Form 1449/A/PTO 02/12/2001 Filing Date INFORMATION DISCLOSURE First Named Inventor D'Amato STATEMENT BY APPLICANT 1616 Group Art Unit (use as many sheets as necessary) Badio, Barbara P. **Examiner Name** 05213-0493 (43170-253692) Attorney Docket Number Sheet of 31 30 OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Examiner Cite item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Initials publisher, city and/or country where published Title: Photoaffinity Labeling & Human Placental Estradiol 17.beta.-dehydrogenase wh 2-243 Author: WANG et al. And 4-azidoestrone, 2- and 4-azidoestradiol (abstract Only) Publ: Shengwu Huaxue Zazhi Pages: 715-718 Vol/Iss: 8 (6) Date: Title: An Optimized Synthesis of 2-Methoxyestradiol, a Naturally Occurring Human 244 Author: WANG, Z. et al. Metabolite with Anticancer Activity Publ: Synth.Commun. Pages: 4431-4437 Vol/Iss: 28 (23) Date: 1998 Title: Tumor angiogenesis: A New Significant and Independent Prognostic Indicator in 245 Author: WEIDNER, N. et al. Early-Stage Breast Carcinoma Publ: Journal of the National Cancer Institute Pages: 1875-1887 Date: 12/16/92 Vol/Iss: 84 Title: Tumor Angiogenesis Correlates with Metastasis in Invasive Prostate Carcinoma Author: WEIDNER, N. et al. 246 Publ: American Journal of Pathology Pages: 401-409 Date: 08/1993 Vol/Iss: 143 (2) Title: Tumor Angiogenesis and Metastasis-Correlation in Invasive Breast Carcinoma Author: WEIDNER, N. et al. 247 New England Journal of Medicine Pages: 1-8 Date: 01/03/91 Vol/Iss: 324 (1) Title: Staphylostatic Activity of Some New Diphenols, Napthols, and Chalcones (Abstract Author: WELSCH et al. 248 Publ: <u>Experientia</u> Pages: 350-351 Date: Vol/Iss: 11 1955 Title: Treatment of Pulmonary Hemangiomatosis with Recombinant Interferon Alfa-2a Author: WHITE et al. 249 The New England Journal of Medicine Pages: 1197-1200 Date: 05/04/89

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		Filing Date	02/12/2001 D'Amato 1616			
		First Named Inventor				
		Group Art Unit				
		Examiner Name	Badio, Barbara P.			
Sheet		31 of 31		Attorney Docket Number	05213-0493 (431	70-253692)
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Examiner Initials	Cite No.¹	Include name item (book, n	nagazine, journal, serial, symp	e author (in CAPITAL LETTERS), title of the article (when appropriate), title of the ne, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published		
	250	Author: WIESE et al. Publ: Journal of Medicinal Chem	Selected A	of the Estrogen Specific Mitoger Analogues of Estradiol-17 \(\beta\): A 3E	O QSAR Study	7 Cells by
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